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DEPARTMENT OF HEALTH AND HUMAN SERVICES

CFN:1125692
Facility ID:222352
Inspection ID #2223520003

Food and Drug Administration
Baltimore District Office
900 Madison Avenue
Baltimore, MD 21201-2199
Telephone: (410) 962-3396

01-BLT-42

September 24, 2001

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Lerla G. Joseph, Facility President
Hull Street Diagnostic Center
1606 Hull Street
Richmond, Virginia 23224

Dear Ms. Joseph:

A representative from the Commonwealth of Virginia under contract to the Food and Drug Administration (FDA) inspected your facility on August 28, 2001. This inspection revealed a serious regulatory problem involving mammography performed at your facility.

Under a United States Federal law, the Mammography Quality Standards Act (MQSA) of 1992, your facility must meet specific requirements for mammography. These requirements help protect the public health by assuring that a facility can perform quality mammography. The inspection revealed the following Level 1 findings:

- **Your facility failed to have in place a system to provide a written report of the mammography examination to the referring health care provider as soon as possible, but no later than 30 days from the date of the mammography examination;**

- **Your facility failed to have in place a system to provide a summary of the mammography report to the patient written in lay terms within 30 days of the mammographic examination;**

- **Your facility failed to have in place a system to communicate serious or highly suggestive cases to the referring health care provider as soon as possible.**

The specific problems noted above appeared on your MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection. These problems are identified as Level 1 findings because they identify a failure to comply with a significant MQSA requirement.

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography performed at your facility, they represent a violation of the law that may result in FDA taking regulatory action without further notice to you.

These actions include, but are not limited to: placing your facility under a Directed Plan of Correction; charging your facility for the cost of on-site monitoring; assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with MQSA standards; suspension or revocation of your facility's FDA certificate; or obtaining a court injunction against further mammography.

It is necessary for you to act on this matter immediately. Please explain to this office in writing within fifteen (15) working days from the date you receive this letter:

- The specific steps you have taken to correct the violations noted in this letter; and
- Each step your facility is taking to prevent the recurrence of similar violations.

Your response should be submitted to: Food and Drug Administration, 900 Madison Avenue, Baltimore, MD, 21201, to the attention of Ms. Anita Richardson, Director, Compliance Branch. .

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you may have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715), or through the Internet at http://www.fda.gov.

If you have technical questions about mammography facility requirements, or about the content of this letter, please feel free to contact Elizabeth A. Laudig at (410) 962-3591, extension 159.

Sincerely,

Lee Bowers
Director, Baltimore District

cc: Stan Orchel, Radiation Safety Specialist
Bureau of Radiological Health
Division of Health Hazards Control
Department of Health, Main Street Station
1500 East Main, Room 240
Richmond, Virginia 23219

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